

Pharmacy Student Rotation in the Food and Drug Administration's Center for Drug Evaluation and Research (CDER), Division of Anti-infective Products

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the drug development, review, and post-marketing phases of drug development.

I. Learning Objectives: Upon completion of this rotation the student will be able to:

- A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.
- B. Distinguish between the three phases of clinical trials in the drug development process.
- C. Discuss ways the FDA makes new drugs available to patients prior to approval.
- D. Outline the post-marketing surveillance mechanisms the FDA uses to assure drugs remain safe and effective for the American people.
- E. Utilize drug information and FDA resources such as Medline, Micromedex, and the Federal Register, and become familiar with what type of information is posted on the FDA's web page and CDER's Internet.
- F. Answer questions /become familiar with the laws, regulations, and guidance documents governing drugs.
- G. Respond to inquiries regarding FDA approved products.

II. Student Requirements: The student will be exposed to a variety of concepts regarding all aspects of pharmaceuticals and the pharmaceutical industry. The program will focus on familiarizing the student with new drug development and the approval process. To meet these objectives the student will be expected to:

- A. Be familiar with current drug news in the media.
- B. Give a presentation or conduct a project assigned by preceptor.
- C. Attend student rotations within the Center for Drug Evaluation and Research.
- D. Fulfill required hours.
- E. Additional requirements will be established the first week of the rotation and assigned based on student interests.